K120828
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APR - 5 2012

510(k) Summary

Biatain Silicone Ag Foam Dressings

The assigned 510(k) number is: _____

510(k) Owner's Name: Coloplast A/S

Contact Person: Rebeka A. Stoltman
Manager, Regulatory Affairs
Coloplast Corp.
1601 West River Road North
Minneapolis, MN 55411

Telephone: (612) 302-4997
Facsimile: (612) 287-4138
Email: usrst@coloplast.com

Date Prepared: March 16, 2012

Device Name and Classification

Trade Name:	Biatain Silicone Ag Foam Dressings
Common Name:	Topical Wound Dressing
Classification:	Unclassified; 21 CFR § 878.4020
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO

Manufacturer

Coloplast A/S
Holtedam 1
3050 Humlebaek, Denmark

Establishment Registration: 9610694
Owner/Operator: 8010144

Device Description

Biatain Silicone Ag Foam Dressings are wound dressings for exuding wounds with delayed healing due to bacteria or where there is a risk of infection. Biatain Ag Foam Dressings consist of a **Top film** (Printed high moisture-permeable barrier polyurethane (PU) film); a **Center part** (Soft, absorbing polyurethane (PU) antimicrobial foam (same Biatain Ag foam from Coloplast cleared via K100218) pads adhered to the top film with hot melt acrylic adhesive to avoid delamination when wet); a **Border part** (Perforated laminate of acrylic adhesive/melt blown polyurethane film/silicone adhesive, where the acrylic adhesive adheres to the top film, and the silicone adhesive is for skin adherence); and a **Release liner:** 3-part release liner that covers both center and border part.

The foam contains silver, which is released upon contact with wound exudate.

The dressings are available in different sizes. The dressing is square-shaped with rounded corners. Foam thickness is 3 mm. Biatain Silicone Ag foam dressing is protected with semi-permeable film backings that are waterproof and provide bacterial barriers.

The dressings are individually-packed in a pouch. All dressings are sterile and are for single use only.

Substantial Equivalence Claim

The modified Coloplast Biatain Silicone Ag Foam Dressings are substantially equivalent in performance, indications, design and materials to Coloplast's currently marketed Biatain Ag Adhesive Dressings, which were cleared under 510(k) K100218.

Indications for Use

Biatain Silicone Ag Foam Dressings are indicated for use in the management of moderately to highly exuding leg ulcers and pressure sores. The dressing can also be used for 2nd degree burns, donor sites, post operative wounds and skin abrasions.

Summary & Conclusions of the Nonclinical Tests Submitted

Substantial equivalency is supported by bench testing compared to the predicate device and biocompatibility testing performed on the subject device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Coloplast A/S
% Coloplast Corporation
Ms. Rebeka Stoltman
1601 West River Road North
Minneapolis, Minnesota 55411

APR - 5 2012

Re: K120828
Trade/Device Name: Biatain Silicone Ag Foam Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: March 16, 2012
Received: March 19, 2012

Dear Ms. Stoltman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120828

Device Name: Biatain Silicone Ag Foam Dressing

Indications for Use:

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Prescription Use X (21 CFR 801 Subpart D)	AND / OR	Over-The-Counter Use ___ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krone for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120828